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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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THE PEOPLE OF THE STATE OF NEW YORK, :
by ANDREW M. CUOMO, Attorney General of :
the State of New York, and THE CITY OF NEW :
YORK, :
----- x

Plaintiffs, :

No.: 07 cv 8434

ANSWER AND JURY DEMAND
OF DEFENDANT MERCK &
CO., INC.

-against- :

MERCK & CO., INC., :

Defendant. :

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Defendant Merck & Co., Inc. ("Merck") answers the Complaint ("Complaint")
herein as follows:

RESPONSE TO "PRELIMINARY STATEMENT"

1. Denies each and every allegation contained in paragraph 1 of the Complaint
except admits that Merck is a leading research-driven pharmaceutical products and
services company that researches, discovers, develops, manufactures and markets a broad
range of innovative pharmaceutical products to improve human health and that Merck
manufactured, marketed and distributed the prescription medicine Vioxx until Merck
voluntarily withdrew Vioxx from the worldwide market on September 30, 2004.

2. Denies each and every allegation contained in the first and third sentences of paragraph 2 of the Complaint except admits that in May 1999 Merck received United States Food & Drug Administration (“FDA”) approval to manufacture and market the prescription medicine Vioxx in a manner consistent with the information contained in the FDA-approved prescribing information and that the FDA later approved Vioxx for the treatment of rheumatoid arthritis in adults, migraine, and juvenile rheumatoid arthritis. Merck respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its indicated uses. Denies each and every allegation contained in the second sentence of paragraph 2 of the Complaint except admits that Vioxx is a selective NSAID and the mechanism of action is believed to be due to inhibition of prostaglandin synthesis via inhibition of an enzyme known as cyclooxygenase-2 (COX-2). Denies each and every allegation contained in the fourth sentence of paragraph 2 of the Complaint except admits that Vioxx was prescribed to millions of patients.

3. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 3 of the Complaint.

4. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 4 of the Complaint.

5. Denies each and every allegation contained in paragraph 5 of the Complaint and avers that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo. Merck further avers that given the availability of alternative therapies and questions raised by the data from that trial, Merck

concluded that a voluntary withdrawal of Vioxx from the worldwide market best served the interests of patients.

6. Denies each and every allegation contained in paragraph 6 of the Complaint.
7. Denies each and every allegation contained in paragraph 7 of the Complaint.
8. Denies each and every allegation contained in paragraph 8 of the Complaint.
9. Denies each and every allegation contained in paragraph 9 of the Complaint except admits that Plaintiffs purport to bring an action for damages but denies that there is any legal or factual basis for relief.

RESPONSE TO "JURISDICTION AND PARTIES"

10. Admits the allegations contained in the first sentence of paragraph 10 of the Complaint. The allegations contained in the second sentence of paragraph 10 of the Complaint are legal conclusions as to which no response is required. Should a response be deemed required, Merck denies each and every allegation contained in said sentence and respectfully refers to the Court to the referenced statutes for their actual language and full text.

11. Upon information and belief, admits the allegations contained in the first sentence of paragraph 11 of the Complaint. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the second and third sentences of paragraph 11 of the Complaint and respectfully refers the Court to the referenced statutes for their actual language and full text.

12. Denies each and every allegation contained in paragraph 12 of the Complaint except admits that Merck is a New Jersey Corporation with its principal place of business

at One Merck Drive, Whitehouse Station, New Jersey and that Merck is authorized to do business in the State of New York.

13. The allegations contained in paragraph 13 of the Complaint are legal conclusions as to which no response is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

RESPONSE TO "FACTUAL ALLEGATIONS"

14. Denies each and every allegation contained in paragraph 14 of the Complaint except admits, upon information and belief, that the Medical Assistance Program in New York State (Medicaid) is jointly funded by the Federal, State and local governments, provides medical assistance and other benefits, including prescription drugs, for low-income individuals and families, that the relevant statute and regulations provide that Medicaid covers medically necessary assistance and benefits, and is administered by the New York State Department of Health.

15. Denies each and every allegation contained in paragraph 15 of the Complaint except admits, upon information and belief, that EPIC is a voluntary New York State sponsored prescription plan for senior citizens who are 65 years of age or older and are not eligible for full Medicaid coverage and that individuals who choose to participate pay a copayment for each drug purchased based on the price of the prescription.

16. Denies the characterization of the allegations contained in paragraph 16 of the Complaint and denies each and every allegation contained in said paragraph except admits that Merck announced the development of a COX-2 specific inhibitor in May 1996, that certain of Merck's products, including Mevacor, Pepcid, and Prilosec, had

expiring patents, and that Monsanto and Pfizer were also developing a COX-2 specific inhibitor.

17. Denies each and every allegation contained in the first sentence of paragraph 17 of the Complaint except admits that in 1996 Merck announced that Vioxx was in clinical trials. Denies each and every allegation contained in the second and third sentences sentences of paragraph 17 of the Complaint, except admits that Merck designed a large-scale, long-term, double-blind gastrointestinal outcomes study named the Vioxx Gastrointestinal Outcomes Research (“VIGOR”) study.

18. Denies each and every allegation contained in paragraph 18 of the Complaint except admits that Plaintiffs purport to quote the referenced memorandum and avers that said quotation is taken out of context.

19. Denies each and every allegation contained in paragraph 19 of the Complaint except admits that Plaintiffs purport to quote the referenced email and avers that said quotation is taken out of context.

20. Denies each and every allegation contained in paragraph 20 of the Complaint except admits that Plaintiffs purport to quote the referenced email and avers that said quotation is taken out of context.

21. Denies each and every allegation contained in paragraph 21 of the Complaint .

22. Denies each and every allegation contained in paragraph 22 of the Complaint except admits that the 1998 Annual Report exists and respectfully refers the Court to the referenced Annual Report for its actual language and full text.

23. Denies each and every allegation contained in paragraph 23 of the Complaint.

24. Denies each and every allegation contained in paragraph 24 of the Complaint except admits that Merck marketed Vioxx in a manner consistent with the information contained in the FDA-approved prescribing information and respectfully refers the Court to the relevant advertisements, the relevant patient product information and the relevant FDA-approved prescribing information for their actual language and full text.

25. Denies each and every allegation in paragraph 25 of the Complaint except admits that the VIGOR study involving Vioxx exists and was concluded in 2000 and respectfully refers the Court to the referenced study for its actual conclusions and full text. Merck further admits that Vioxx has been proven in randomized clinical trials to reduce the rate of certain gastrointestinal events compared to naproxen.

26. Denies each and every allegation in paragraph 26 of the Complaint except admits that the VIGOR study involving Vioxx exists and respectfully refers the Court to the referenced study for its actual conclusions and full text.

27. Denies each and every allegation in paragraph 27 of the Complaint except admits that the VIGOR study and certain earlier studies involving Vioxx exist and respectfully refers the Court to the referenced studies for their actual conclusions and full text.

28. Denies each and every allegation in paragraph 28 of the Complaint except admits that the VIGOR study involving Vioxx exists and respectfully refers the Court to the referenced study for its actual conclusions and full text.

29. Denies each and every allegation contained in the first and second sentences of paragraph 29 of the Complaint except admits that on February 8, 2001, the Arthritis Advisory Committee met and discussed, among other things, the VIGOR data. Merck

denies each and every allegation contained in the third sentence of paragraph 29 of the Complaint except admits the existence of the referenced memorandum dated February 1, 2001, and respectfully refers the Court to said memorandum for its actual language and full text.

30. Denies each and every allegation in paragraph 30 of the Complaint and respectfully refers the Court to the referenced findings for their actual conclusions and full text.

31. Denies each and every allegation contained in paragraph 31 of the Complaint except admits that in March 2001, Merck filed a patent application and respectfully refers the Court to the referenced application for its actual language and full text.

32. Denies each and every allegation contained in paragraph 32 of the Complaint.

33. Denies each and every allegation contained in paragraph 33 of the Complaint.

34. Denies each and every allegation contained in paragraph 34 of the Complaint.

35. Denies each and every allegation contained in paragraph 35 of the Complaint and respectfully refers the Court to the referenced approved resources for the full language and directions presented to Merck's field representatives.

36. Denies each and every allegation contained in paragraph 36 of the Complaint.

37. Denies each and every allegation contained in paragraph 37 of the Complaint except admits that Merck did have national instructions and communications to its field representatives and that these instructions and communications would be delivered to field representatives in New York.

38. Denies each and every allegation contained in paragraph 38 of the Complaint except admits the existence of the referenced approved resource but avers that the quotes

are taken out of context and respectfully refers the Court to Merck's approved resources for the full language and directions presented to its field representatives.

39. Denies each and every allegation contained in paragraph 39 of the Complaint except admits the existence of the referenced document but avers that the quotes and instructions are taken out of context and respectfully refers the Court to the referenced document and accompanying instructions for the full language and directions presented to its field representatives.

40. Denies each and every allegation contained in paragraph 40 of the Complaint except admits the existence of the referenced approved resource and respectfully refers the Court to Merck's approved resources for the full language and directions presented to its field representatives.

41. Denies each and every allegation contained in paragraph 41 of the Complaint except admits that the New York Times article referenced in the first sentence exists and respectfully refers the Court to said article for the full language and text and admits that the approved resource referenced in the second and third sentences exists and respectfully refers the Court to Merck's approved resources for the full language and directions presented to its field representatives.

42. Denies each and every allegation contained in paragraph 42 of the Complaint except admits the existence of the referenced approved resource and respectfully refers the Court to Merck's approved resources for the full language and directions presented to its field representatives.

43. Denies each and every allegation contained in paragraph 43 of the Complaint except admits the existence of the referenced article and respectfully refers the Court to

said article for its full text and language, and further admits that the existence of this article was communicated to its field representatives on August 21, 2001.

44. Denies each and every allegation contained in paragraph 44 of the Complaint except admits the existence of the referenced approved resource and respectfully refers the Court to Merck's approved resources and instructions for the full language and directions presented to its field representatives.

45. Denies each and every allegation contained in paragraph 45 of the Complaint and respectfully refers the Court to Merck's responses and statements regarding the referenced JAMA article for their full text and language.

46. Denies each and every allegation contained in paragraph 46 of the Complaint except admits Plaintiffs purport to quote a statement but avers that said quotation is taken out of context and respectfully refers the Court to the source of the referenced quotation for its actual language and full text.

47. Denies each and every allegation contained in paragraph 47 of the Complaint except admits the existence of the referenced approved resource and respectfully refers the Court to Merck's approved resources and instructions for the full language and directions presented to its field representatives.

48. Denies each and every allegation contained in paragraph 48 of the Complaint except admits the existence of the referenced abstract and the approved resource and respectfully refers the Court to said article for the full language and text and to Merck's approved resources for the full language and directions presented to its field representatives.

49. Denies each and every allegation contained in paragraph 49 of the Complaint except admits the existence of the referenced approved but avers that the quotes are taken out of context and respectfully refers the Court to Merck's approved resources and instructions for the full language and directions presented to its field representatives.

50. Denies each and every allegation contained in paragraph 50 of the Complaint except admits that the observational study and the approved resource referenced in said paragraph exist and respectfully refers the Court to said observational study for the full language and text and to Merck's approved resources for the full language and directions presented to its field representatives.

51. Denies each and every allegation contained in paragraph 51 of the Complaint except admits the existence of the referenced approved resource but avers that the quotes are taken out of context and respectfully refers the Court to Merck's approved resources and instructions for the full language and directions presented to its field representatives. Merck further avers that it marketed Vioxx in a manner consistent with the information contained in the FDA-approved prescribing information and respectfully refers the Court to the relevant advertisements, the relevant patient product information and the relevant FDA-approved prescribing information for their actual language and full text.

52. Denies each and every allegation contained in paragraph 52 of the Complaint except admits the existence of the referenced approved resources and respectfully refers the Court to Merck's approved resources and instructions for the full language and directions presented to its field representatives.

53. Denies each and every allegation contained in paragraph 53 of the Complaint except admits that Merck did have national instructions and communications to its field

representatives and that these instructions and communications would be delivered to field representatives in New York and respectfully refers the Court to these approved resources for the full language and directions presented to Merck's field representatives.

54. Denies each and every allegation contained in paragraph 54 of the Complaint except admits the existence of the referenced publication and respectfully refers the Court to said publication for its actual language and full text.

55. Denies each and every allegation contained in paragraph 55 of the Complaint except admits that Merck received preliminary data from the VIGOR trial in March 2000 and respectfully refers the Court to Merck's May 18, 2000 submission to the NEJM and to the published article for the actual language and full text.

56. Denies each and every allegation contained in paragraph 56 of the Complaint.

57. Denies each and every allegation contained in paragraph 57 of the Complaint.

58. Denies each and every allegation contained in paragraph 58 of the Complaint.

59. Denies each and every allegation contained in paragraph 59 of the Complaint except admits that Dr. Singh was a gastroenterologist associated with Stanford University and respectfully refers the Court to Dr. Singh's Curriculum Vitae.

60. Denies each and every allegation contained in paragraph 60 of the Complaint, except admits that Dr. Singh was a speaker on behalf of Merck.

61. Denies each and every allegation contained in paragraph 61 of the Complaint except admits that Plaintiffs purport to quote various statements but avers that said quotations are taken out of context and respectfully refers the Court to the sources of the referenced quotations for their actual language and full text.

62. Denies each and every allegation contained in paragraph 62 of the Complain except admits that in 2000, Dr. Sherwood contacted Dr. James Fries (Dr. Singh's immediate supervisor at Stanford) to discuss certain statements that Dr. Singh had been making in presentations to physicians that Merck perceived to be inappropriate.

63. Denies each and every allegation contained in paragraph 63 except admits that Plaintiffs purport to quote various statements but avers that said quotations are taken out of context and respectfully refers the Court to the sources of the referenced quotations for their actual language and full text.

64. Denies each and every allegation contained in paragraph 64 of the Complaint.

65. Denies each and every allegation contained in paragraph 65 of the Complaint and respectfully refers the Court to the referenced press releases for their actual language and full text.

66. Denies each and every allegation contained in paragraph 66 of the Complaint except admits that Merck sent a letter regarding Vioxx to physicians in August 2001 and respectfully refers the Court to that letter for its actual language and full text.

67. Denies each and every allegation contained in paragraph 67 of the Complaint except admits that Merck marketed Vioxx in a manner consistent with the information contained in the FDA-approved prescribing information and respectfully refers the Court to the relevant advertisements, the relevant patient product information and the relevant FDA-approved prescribing information for their actual language and full text.

68. Denies each and every allegation contained in paragraph 68 of the Complaint except admits that Merck marketed Vioxx in a manner consistent with the information contained in the FDA-approved prescribing information and respectfully refers the Court

to the relevant advertisements, the relevant patient product information and the relevant FDA-approved prescribing information for their actual language and full text.

69. Denies each and every allegation contained in paragraph 69 of the Complaint except admits that Merck marketed Vioxx in a manner consistent with the information contained in the FDA-approved prescribing information and respectfully refers the Court to the relevant advertisements, the relevant patient product information and the relevant FDA-approved prescribing information for their actual language and full text

70. Denies each and every allegation contained in paragraph 70 of the Complaint except admits that Merck marketed Vioxx in a manner consistent with the information contained in the FDA-approved prescribing information and respectfully refers the Court to the relevant advertisements, the relevant patient product information and the relevant FDA-approved prescribing information for their actual language and full text.

71. Denies each and every allegation contained in paragraph 71 of the Complaint.

72. Merck admits that patients rely on the professional judgment of their physicians in deciding whether to consent to and purchase treatment, and further avers that the decision to use any particular prescription medication is an individual determination made by a patient and his or her physician. To the extent not admitted, Merck denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 72 of the Complaint, and respectfully refers the Court to the relevant professional standards for New York physicians for their actual language and full text.

73. Denies each and every allegation contained in paragraph 73 of the Complaint.

74. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 74 of the Complaint except admits that, upon information and belief, Vioxx was prescribed to New York consumers, some of whom were enrolled in the New York Medicaid and/or EPIC programs.

75. Denies each and every allegation contained in paragraph 75 of the Complaint.

76. Denies each and every allegation contained in paragraph 76 of the Complaint.

77. Denies each and every allegation contained in paragraph 77 of the Complaint.

**RESPONSE TO "FIRST CAUSE OF ACTION
OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS
(N.Y. Social Services Law § 145-b)"**

78. With respect to the allegations contained in paragraph 78 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 77 of this Answer with the same force and effect as though set forth here in full.

79. The allegations contained in paragraph 79 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.

80. Denies each and every allegation contained in paragraph 80 of the Complaint and respectfully refers the Court to the referenced statute for its actual language and full text.

81. Denies each and every allegation contained in paragraph 81 of the Complaint and respectfully refers the Court to the referenced statute for its actual language and full text.

**RESPONSE TO “SECOND CAUSE OF ACTION
NEW YORK FALSE CLAIMS ACT
N.Y. Finance Law § 189(1)(a)”**

82. With respect to the allegations contained in paragraph 82 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 77 of this Answer with the same force and effect as though set forth here in full.

83. Denies each and every allegation contained in paragraph 83 of the Complaint except admits that Plaintiffs seek certain relief but denies that there is any legal or factual basis for said relief and respectfully refers the Court to the referenced statutes for their actual language and full text.

84. Denies each and every allegation contained in paragraph 84 of the Complaint.

85. Denies each and every allegation contained in paragraph 85 of the Complaint.

86. Denies each and every allegation contained in paragraph 86 of the Complaint.

87. Denies each and every allegation contained in paragraph 87 of the Complaint.

**RESPONSE TO “THIRD CAUSE OF ACTION
NEW YORK FALSE CLAIMS ACT
N.Y. Finance Law § 189(1)(b)”**

88. With respect to the allegations contained in paragraph 88 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 77 of this Answer with the same force and effect as though set forth here in full.

89. Denies each and every allegation contained in paragraph 89 of the Complaint except admits that Plaintiffs seek certain relief but denies that there is any legal or factual basis for said relief and respectfully refers the Court to the referenced statutes for their actual language and full text.

90. Denies each and every allegation contained in paragraph 90 of the Complaint.

91. Denies each and every allegation contained in paragraph 91 of the Complaint.

92. Denies each and every allegation contained in paragraph 92 of the Complaint.

93. Denies each and every allegation contained in paragraph 93 of the Complaint and respectfully refers the Court to the referenced statute for its actual language and full text.

**RESPONSE TO “FOURTH CAUSE OF ACTION
REPEATED AND PERSISTENT FRAUD
N.Y. Executive Law § 63(12)”**

94. With respect to the allegations contained in paragraph 94 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 93 of this Answer with the same force and effect as though set forth here in full.

95. The allegations contained in paragraph 95 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.

96. Denies each and every allegation contained in paragraph 96 of the Complaint and respectfully refers the Court to the referenced statute for its actual language and full text.

**RESPONSE TO "FIFTH CAUSE OF ACTION
REPEATED AND PERSISTENT ILLEGAL CONDUCT:
OBTAINING PUBLIC FUNDS BY FALSE STATEMENTS
N.Y. Executive Law § 63(12)"**

97. With respect to the allegations contained in paragraph 97 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 93 of this Answer with the same force and effect as though set forth here in full.

98. The allegations contained in paragraph 98 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph and respectfully refers the Court to the referenced statute for its actual language and full text.

99. Denies each and every allegation contained in paragraph 99 of the Complaint and respectfully refers the Court to the referenced statute for its actual language and full text.

100. Denies each and every allegation contained in paragraph 100 of the Complaint and respectfully refers the Court to the referenced statute for its actual language and full text.

**RESPONSE TO "SIXTH CAUSE OF ACTION
NEW YORK CITY FALSE CLAIMS ACT
N.Y.C. Admin. Code §§ 7-801 et seq."**

101. With respect to the allegations contained in paragraph 101 of the Complaint, Merck repeats and re-alleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 77 of this Answer with the same force and effect as though set forth here in full.

102. Denies each and every allegation contained in paragraph 102 of the Complaint except admits that Plaintiffs seek certain relief but denies that there is any legal or factual basis for said relief and respectfully refers the Court to the referenced statutes for their actual language and full text.

103. Denies each and every allegation contained in paragraph 103 of the Complaint.

104. Denies each and every allegation contained in paragraph 104 of the Complaint.

105. Denies each and every allegation contained in paragraph 105 of the Complaint.

106. Denies each and every allegation contained in paragraph 106 of the Complaint.

RESPONSE TO "PRAYER FOR RELIEF"

107. Plaintiffs' "Prayer For Relief" section of the Complaint, including subparagraphs A through J, is not an allegation and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in the "Prayer For Relief" section of Plaintiffs' Complaint, including subparagraphs A through J, and denies that Plaintiffs are entitled to the relief requested.

**AS FOR A FIRST
DEFENSE, MERCK ALLEGES:**

108. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and statutes of repose and is otherwise untimely.

**AS FOR A SECOND
DEFENSE, MERCK ALLEGES:**

109. The Complaint fails to state a claim upon which relief can be granted.

**AS FOR A THIRD
DEFENSE, MERCK ALLEGES:**

110. The claims of the Plaintiffs may be barred, in whole or in part, from recovery because they have made statements or taken actions that preclude them from asserting claims or constitute a waiver of their claims.

**AS FOR A FOURTH
DEFENSE, MERCK ALLEGES:**

111. The claims of the Plaintiffs may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

**AS FOR A FIFTH
DEFENSE, MERCK ALLEGES:**

112. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**AS FOR A SIXTH
DEFENSE, MERCK ALLEGES:**

113. If Plaintiffs' payees have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were cause in whole or in part through the operation of nature or other intervening cause or causes.

**AS FOR A SEVENTH
DEFENSE, MERCK ALLEGES:**

114. To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**AS FOR AN EIGHTH
DEFENSE, MERCK ALLEGES:**

115. To the extent that Plaintiffs assert claims based upon an alleged failure by Merck to warn Plaintiffs directly of alleged dangers associated with the use of Vioxx,

such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**AS FOR A NINTH
DEFENSE, MERCK ALLEGES:**

116. If Plaintiffs' payees have sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiffs' payees knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**AS FOR A TENTH
DEFENSE, MERCK ALLEGES:**

117. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**AS FOR AN ELEVENTH
DEFENSE, MERCK ALLEGES:**

118. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiffs' payees' misuse or abuse of Vioxx.

**AS FOR A TWELFTH
DEFENSE, MERCK ALLEGES:**

119. If Plaintiffs have sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiffs' payees' pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

**AS FOR A THIRTEENTH
DEFENSE, MERCK ALLEGES:**

120. To the extent Plaintiffs settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**AS FOR A FOURTEENTH
DEFENSE, MERCK ALLEGES:**

121. To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**AS FOR A FIFTEENTH
DEFENSE, MERCK ALLEGES:**

122. Plaintiffs' claims of fraud are barred by reason of Plaintiffs' failure to allege the circumstances constituting fraud with particularity, as required by Section 3013 of the New York Civil Practice Law and Rules and Rule 9(b) of the Federal Rules of Civil Procedure.

**AS FOR A SIXTEENTH
DEFENSE, MERCK ALLEGES:**

123. Plaintiffs' claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A SEVENTEENTH
DEFENSE, MERCK ALLEGES:**

124. Plaintiffs' claims are barred in whole or in part by the First Amendment.

**AS FOR A EIGHTEENTH
DEFENSE, MERCK ALLEGES:**

125. Plaintiffs' claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**AS FOR A NINETEENTH
DEFENSE, MERCK ALLEGES:**

126. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

**AS FOR A TWENTIETH
DEFENSE, MERCK ALLEGES:**

127. This case is more appropriately brought in a different venue.

**AS FOR A TWENTY-FIRST
DEFENSE, MERCK ALLEGES:**

128. The claims of Plaintiffs may be barred, in whole or in part, from recovery because, in this or other courts, they have brought actions and have received judgments on parts of some or all claims asserted herein.

**AS FOR A TWENTY-SECOND
DEFENSE, MERCK ALLEGES:**

129. The claims of Plaintiffs may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

**AS FOR A TWENTY-THIRD
DEFENSE, MERCK ALLEGES:**

130. The claims of Plaintiffs may be barred, in whole or in part, from recovery by release as to their claims.

**AS FOR A TWENTY-FOURTH
DEFENSE, MERCK ALLEGES:**

131. The claims of Plaintiffs may be barred, in whole and in part, by the doctrine of laches.

**AS FOR A TWENTY-FIFTH
DEFENSE, MERCK ALLEGES:**

132. The claims of Plaintiffs are barred, in whole or in part, by their failure to mitigate damages.

**AS FOR A TWENTY-SIXTH
DEFENSE, MERCK ALLEGES:**

133. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

**AS FOR A TWENTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

134. The claims of Plaintiffs may be barred, in whole or in part, from recovery, due to spoliation of evidence.

**AS FOR A TWENTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

135. The claims of Plaintiffs may be barred, in whole or in part, by the governing state laws.

**AS FOR A TWENTY-NINTH
DEFENSE, MERCK ALLEGES:**

136. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

**AS FOR A THIRTIETH
DEFENSE, MERCK ALLEGES:**

137. Plaintiffs have not sustained any injury or damages compensable at law.

**AS FOR A THIRTY-FIRST
DEFENSE, MERCK ALLEGES:**

138. To the extent that Plaintiffs seek exemplary or punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

**AS FOR A THIRTY-SECOND
DEFENSE, MERCK ALLEGES:**

139. To the extent that Plaintiffs seek exemplary or punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of exemplary or punitive damages is barred.

**AS FOR A THIRTY-THIRD
DEFENSE, MERCK ALLEGES:**

140. Plaintiffs' demand for exemplary or punitive damages is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A THIRTY-FOURTH
DEFENSE, MERCK ALLEGES:**

141. Plaintiffs' claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-FIFTH
DEFENSE, MERCK ALLEGES:**

142. Plaintiffs' claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or

pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-SIXTH
DEFENSE, MERCK ALLEGES:**

143. Plaintiffs' claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

**AS FOR A THIRTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

144. Plaintiffs' claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**AS FOR A THIRTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

145. Plaintiffs' claims are barred by the doctrine of contributory negligence.

**AS FOR A THIRTY-NINTH
DEFENSE, MERCK ALLEGES:**

146. Plaintiffs' claims are not suitable for joinder.

**AS FOR A FORTIETH
DEFENSE, MERCK ALLEGES:**

147. With respect to each of Plaintiffs' claims, all product(s) which are the subject matter of this action were prepared by Merck and provided by Merck, including their labels and packaging, pursuant to the approval of the appropriate federal agencies and applicable statutes and regulations; approval of preparation of said product(s) was obtained in compliance with all requirements pertaining to the preparation and/or distribution of such product(s) and was accomplished pursuant to acceptable standards of conduct.

**AS FOR A FORTY-FIRST
DEFENSE, MERCK ALLEGES:**

148. At all times relevant herein, any product(s) which are the subject matter of this action processed and distributed by Merck in the State of New York, the City of New York or in the United States were processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further were processed and distributed in accordance with and pursuant to all applicable regulations of the federal Food & Drug Administration (“FDA”).

**AS FOR A FORTY-SECOND
DEFENSE, MERCK ALLEGES:**

149. Plaintiffs may be barred, in whole or in part, from pursuing this action because of the existence of a prior pending action in another court.

**AS FOR A FORTY-THIRD
DEFENSE, MERCK ALLEGES:**

150. Plaintiffs' tort-based claims are barred by the economic loss doctrine.

**AS FOR A FORTY-FOURTH
DEFENSE, MERCK ALLEGES:**

151. Plaintiffs' claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

**AS FOR A FORTY-FIFTH
DEFENSE, MERCK ALLEGES:**

152. Plaintiffs cannot recover in the capacity in which they have sued because they are not the real-party-in-interest with respect to Plaintiffs' claims.

**AS FOR A FORTY-SIXTH
DEFENSE, MERCK ALLEGES:**

153. The federal FDA has implemented a comprehensive regulatory scheme governing the safety and efficacy of prescription drugs. Vioxx, the drug at issue in this

case, was approved by the FDA pursuant to the applicable statutes and regulations. The labeling for Vioxx was also approved by the FDA, and the marketing was conducted in conformity with the FDA's rules and regulations. Such actions and federal statutes and regulations bar and preempt all of Plaintiffs' claims under state law.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
October 3, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

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